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Attorneys for Defendants Apotex, Inc. and Apotex Corp.

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

TEVA PHARMACEUTICAL INDUSTRIES	:	
LTD. and TEVA PHARMACEUTICALS	:	
USA, INC.,	:	
	:	Civil Action No.
Plaintiffs,	:	3:07-cv-05514-GEB-JJH
	:	
v.	:	
	:	
APOTEX, INC. and APOTEX CORP.,	:	
	:	
Defendants.	:	
	:	

**DEFENDANTS' APOTEX, INC. AND APOTEX CORP.'S ANSWER, AFFIRMATIVE
DEFENSES AND COUNTERCLAIMS**

Defendants, Apotex, Inc. and Apotex Corp. (collectively, "Apotex"), by counsel, as for its answers to the Complaint of Plaintiffs Teva Pharmaceutical Industries Ltd. and Teva Pharmaceuticals USA, Inc. (collectively "Plaintiffs"), state and allege as follows.

1. Apotex lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 1, and therefore, denies them.

2. Apotex lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 2, and therefore, denies them.

3. Apotex admits that Defendant Apotex, Inc. is a Canadian corporation having a place of business at 150 Signet Drive, Toronto, Canada M9L 1T9. Apotex admits this Court has personal jurisdiction over Apotex, Inc. for the purposes of this action, and denies the remaining allegations of paragraph 3.

4. Apotex admits that Defendant Apotex Corp. is a Delaware corporation having a place of business at 2400 N. Commerce Parkway, Suite 400, Weston, Florida 33326. Apotex admits this Court has personal jurisdiction over Apotex Corp. for the purposes of this action, and denies the remaining allegations of paragraph 4.

5. Apotex admits that paragraph 5 purports to state a cause of action against Apotex for patent infringement arising under the Patent Laws of the United States, Title 35, U.S.C. § 1 *et seq.* and seeking damages and injunctive relief under 35 U.S.C. §§ 271 and 281-285, and denies the remaining allegations of paragraph.

6. The allegations of paragraph 6 state only a legal conclusion, to which no response is required.

7. The allegations of paragraph 7 state only a legal conclusion, to which no response is required.

8. The allegations of paragraph 8 state only a legal conclusion, to which no response is required. Apotex admits this Court has personal jurisdiction over Apotex, Inc. and Apotex Corp. for the purposes of this action.

9. The allegations of paragraph 9 state only a legal conclusion, to which no response is required.

10. Apotex lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 10, and therefore, denies them.

11. Apotex admits that a copy of the '997 Patent is attached as Exhibit A, but lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 11, and therefore, denies them.

12. Apotex admits that a copy of the '008 Patent is attached as Exhibit B, but lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 12, and therefore, denies them.

13. Apotex admits that the '997 and '008 Patents include claims referring to processes for preparing carvedilol, but otherwise lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 13, and therefore, denies them.

14. Apotex admits that a copy of the '184 Patent is attached as Exhibit C, but lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 14, and therefore, denies them.

15. Apotex admits that the '184 Patent includes claims referring to processes for preparing carvedilol Form II, but otherwise lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 15, and therefore, denies them.

16. Apotex admits that a copy of the '942 Patent is attached as Exhibit D, but lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 16, and therefore, denies them.

17. Apotex admits that the '942 Patent includes claims referring to Carvedilol HCl Hydrate, but otherwise lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 17, and therefore, denies them.

18. Apotex admits that carvedilol is a pharmaceutical compound used in treatment of congestive heart failure, that carvedilol is the active pharmaceutical ingredient in the product sold by GlaxoSmithKline under the trade name COREG®, and that COREG® is listed in the FDA's list of "Approved Drug Products With Therapeutic Equivalence Evaluations." The remaining allegations of paragraph 18 state only a legal conclusion, to which no response is required.

19. Apotex lacks knowledge or information sufficient to form a belief as to the truth of allegations in paragraph 19, and therefore, denies them. The remaining allegations of paragraph 19 state only a legal conclusion, to which no response is required.

20. Apotex lacks knowledge or information sufficient to form a belief as to the truth of allegations in paragraph 20, and therefore, denies them. The remaining allegations of paragraph 20 state only a legal conclusion, to which no response is required.

21. Apotex admits the allegations of paragraph 21.

22. Apotex admits the allegations of paragraph 22.

23. Apotex admits the allegations of paragraph 23.

24. Apotex lacks knowledge or information sufficient to form a belief as to the truth of allegations in paragraph 24, and therefore, denies them. The remaining allegations of paragraph 24 state only a legal conclusion, to which no response is required.

25. Apotex admits the allegations of paragraph 25.

26. Apotex admits the allegations of paragraph 26.

27. Apotex admits that it is engaged in the importation, manufacture, and sale of generic carvedilol tablets in the United States. Apotex lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 27, and therefore, denies them.

28. Apotex denies the allegations of paragraph 28.

29. Apotex admits that Plaintiffs notified Apotex of the patents-in-suit and requested information relating to the generic carvedilol sold by Apotex. Apotex denies the remaining allegations of paragraph 29.

30. Apotex admits that it has not provided Plaintiffs with requested samples or information relating the generic carvedilol sold by Apotex. Apotex denies the remaining allegations of paragraph 30.

31. Apotex denies the allegations of paragraph 31.

32. Apotex denies the allegations of paragraph 32.

33. Apotex denies the allegations of paragraph 33.

COUNT 1

34. Apotex repeats and realleges its responses to paragraphs 1-33 as if fully set forth herein.

35. Apotex denies the allegations of paragraph 35.

PRAYER FOR RELIEF

Apotex denies that Plaintiffs are entitled to the relief requested in the Complaint.

AFFIRMATIVE DEFENSES

36. Apotex has not and does not infringe any valid and enforceable claims of the '997, '008, '184, and '942 patents.

37. Apotex has not, does not, and will not induce or contribute to any infringement of any claim of the '997, '008, '184, and '942 patents and is not liable for any act that would be held to be any act of infringement of the '997, '008, '184, and '942 patents.

38. The claims of the '997, '008, '184, and '942 patents are invalid under one or more provisions of 35 U.S.C. § 1, *et seq.*, including but not limited to, §§ 102, 103, 112 and 282 and double patenting.

39. The claims of the '997, '008, '184, and '942 patents are unenforceable on the grounds of inequitable conduct.

40. The claims of the '997, '008, '184, and '942 patents are unenforceable on the grounds of patent misuse and/or unclean hands.

41. The claims of the '997, '008, '184, and '942 patents are unenforceable on the grounds of estoppel, waiver and/or laches.

42. Plaintiffs are barred from obtaining the requested relief pursuant to one or more provisions of 35 U.S.C. § 1, *et seq.*, including but not limited to §§ 286 and 287.

43. Plaintiffs are barred from obtaining the requested relief on the grounds of equitable estoppel.

44. Plaintiffs have not suffered any damages.

45. Plaintiffs are not suffering an irreparable injury.

46. Apotex reserves the right to assert such other defenses as may appear as discovery proceeds in this case.

COUNTERCLAIMS

47. Apotex counterclaims against Plaintiffs pursuant to the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §2201, *et seq.*

48. These counterclaims arise out of the same transactions and occurrences that are the subject of the claims asserted in the Complaint in the above-captioned action. Jurisdiction in this Court is proper pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202 and Rule 13 of the Federal Rules of Civil Procedure.

49. Plaintiffs, having brought suit against Apotex, have submitted itself to the jurisdiction of this Court. Venue in this Court is proper pursuant to 28 U.S.C. § 1391(c)-(d).

First Counterclaim – Declaration of Invalidity

50. Apotex realleges paragraphs 47-49 of its Counterclaims as if set forth specifically herein.

51. U.S. Patent No. 6,699,997 is invalid for failing to comply with the requirements of the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, including but not limited to, §§ 102, 103 and 112.

Second Counterclaim – Declaration of Invalidity

52. Apotex realleges paragraphs 47-51 of its Counterclaims as if set forth specifically herein.

53. U.S. Patent No. 7,126,008 is invalid for failing to comply with the requirements of the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, including but not limited to, §§ 102, 103 and 112.

Third Counterclaim – Declaration of Invalidity

54. Apotex realleges paragraphs 47-53 of its Counterclaims as if set forth specifically herein.

55. U.S. Patent No. 6,710,184 is invalid for failing to comply with the requirements of the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, including but not limited to, §§ 102, 103 and 112.

Fourth Counterclaim – Declaration of Invalidity

56. Apotex realleges paragraphs 47-55 of its Counterclaims as if set forth specifically herein.

57. U.S. Patent No. 7,056,942 is invalid for failing to comply with the requirements of the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, including but not limited to, §§ 102, 103 and 112.

Fifth Counterclaim – Declaration of Noninfringement

58. Apotex realleges paragraphs 47-57 of its Counterclaims as if set forth specifically herein.

59. Apotex has not infringed, is not infringing, and will not infringe any valid and enforceable claim of U.S. Patent No. 6,699,997 and is not liable for any act of infringement of the '997 patent.

Sixth Counterclaim – Declaration of Noninfringement

60. Apotex realleges paragraphs 47-59 of its Counterclaims as if set forth specifically herein.

61. Apotex has not infringed, is not infringing, and will not infringe any valid and enforceable claim of U.S. Patent No. 7,126,008 and is not liable for any act of infringement of the '008 patent.

Seventh Counterclaim – Declaration of Noninfringement

62. Apotex realleges paragraphs 47-61 of its Counterclaims as if set forth specifically herein.

63. Apotex has not infringed, is not infringing, and will not infringe any valid and enforceable claim of U.S. Patent No. 6,710,184 and is not liable for any act of infringement of the '184 patent.

Eighth Counterclaim – Declaration of Noninfringement

64. Apotex realleges paragraphs 47-63 of its Counterclaims as if set forth specifically herein.

65. Apotex has not infringed, is not infringing, and will not infringe any valid and enforceable claim of U.S. Patent No. 7,056,942 and is not liable for any act of infringement of the '942 patent.

Ninth Counterclaim – Declaration of Unenforceability

66. Apotex realleges paragraphs 47-65 of its Counterclaims as if set forth specifically herein.

67. U.S. Patent Nos. 6,699,997 and 7,056,942 are in the same patent family as U.S. Patent No. 7,126,008.

68. At the time of the prosecution of the application that resulted in U.S. Patent No. 7,126,008, the relevant prior art, including U.S. Patent Nos. 4,503,067 and U.S. 4,824,963, concerned carvedilol prepared by processes that would render the patent invalid.

69. During the prosecution of U.S. Patent No. 7,126,008, Plaintiffs did not disclose and mischaracterized the relevant prior art.

70. Plaintiffs' failure to disclose and mischaracterization of the relevant prior art were material.

71. Plaintiffs failed to disclose and mischaracterized the relevant prior art with the intent to deceive the U.S. Patent and Trademark Office.

72. Plaintiffs are aware that U.S. Patent No. 7,126,008 was unlawfully obtained and is invalid, yet have filed lawsuits asserting this patent.

73. Plaintiffs actions regarding obtaining and asserting U.S. Patent Nos. 7,126,008 constitute inequitable conduct and patent misuse, thereby rendering the '008, '997, and '942 patents unenforceable.

Tenth Counterclaim – Unfair Competition

74. Apotex realleges paragraphs 47-73 of its Counterclaims as if set forth specifically herein.

75. Teva purposely did not properly investigate Apotex's products in order assess infringement prior to filing the Complaint in furtherance of a strategy of filing lawsuits irrespective of the merits of those lawsuits.

76. By engaging in the actions set forth hereinabove, including but not limited to filing suit without properly investigating Apotex's products and asserting patents that Plaintiffs know are invalid and/or unenforceable, Plaintiffs have engaged in acts constituting unlawful commercial practices under New Jersey's unfair competition law.

**Eleventh Counterclaim – Tortious Interference
With Prospective Economic Advantage**

77. Apotex realleges paragraphs 47-76 of its Counterclaims as if set forth specifically herein.

78. By engaging in the actions set forth hereinabove, including but not limited to filing suit without properly investigating Apotex's products and asserting patents that Plaintiffs know are invalid and/or unenforceable, Plaintiffs have intentionally interfered with Apotex's present and future business interests with respect to making and selling products containing carvedilol.

**Twelfth Counterclaim - Violation of Sherman Act,
15 U.S.C. § 2 – Monopolization and Attempted Monopolization**

79. Apotex realleges paragraphs 47-78 of its Counterclaims as if set forth specifically herein.

80. As set forth hereinabove, Plaintiffs engaged in inequitable conduct when obtaining U.S. Patent Nos. 7,126,008.

81. As further set forth hereinabove, Plaintiffs have filed this lawsuit knowing that U.S. Patent Nos. 4,503,067, U.S. 4,824,963, and 7,126,008 are invalid and/or unenforceable. Plaintiffs have filed similar complaints asserting these patents against many other parties.

82. As further set forth hereinabove, Plaintiffs purposely did not investigate Apotex's products in order to assess infringement of the patents-in-suit prior to filing the Complaint. Similarly, Plaintiffs purposely did not investigate other parties' products prior to filing similar complaints against those parties. Plaintiffs have done so in order to be able to file lawsuits irrespective of the merits of those suits.

83. Plaintiffs improperly obtained the patents-in-suit and used them to file lawsuits against these parties irrespective of the merits of those suits in furtherance of a strategy of making it economically disadvantageous for these parties to enter and/or remain in the market for carvedilol products due to the cost and uncertainty of litigation. Plaintiffs use this strategy to prevent these parties from legitimately entering the market for carvedilol in the United States or force these parties to purchase the active pharmaceutical ingredient for their carvedilol products from Plaintiffs.

84. Plaintiffs' conduct constitutes illegal, unfair, predatory conduct calculated to prevent competition in the market for carvedilol in violation of 15 U.S.C. § 2. Through this

conduct, Plaintiffs have willfully maintained their monopoly of the market for carvedilol in the United States or, with specific intent and dangerous probability of success, have attempted to monopolize the market for carvedilol in the United States. Further, through this conduct, Plaintiffs have erected and attempted to erect artificial barriers to entry, such as the threat of injunction, litigation costs, and royalty payments, by others into the market for carvedilol in the United States.

85. Plaintiffs' conduct has harmed and continues to cause harm to competition in the market for carvedilol products and consumers of those products.

86. Plaintiffs' conduct has harmed and continues to cause harm to Apotex by causing uncertainty in the marketplace and subjecting Apotex to legal fees and expenses in defending this action.

WHEREFORE, Apotex seeks judgment against Plaintiffs as follows:

- A. That Plaintiffs' Complaint, and all of its causes of action, be dismissed with prejudice;
- B. That judgment be entered declaring that U.S. Patent Nos. 6, 699,997, 6,710,184, 7,056,942 and 7,126,008 are invalid and/or unenforceable;
- C. That judgment be entered declaring that U.S. Patent Nos. 6, 699,997, 6,710,184, 7,056,942 and 7,126,008 are not infringed by Apotex;
- D. That this be declared an exceptional case, and that Apotex be awarded its attorneys' fees and costs pursuant to 35 U.S.C. §285;

E. That judgment be entered declaring that Plaintiffs have engaged in unfair competition, tortious interference with Apotex's prospective economic advantage, and violations of 15 U.S.C. § 2, and enjoining Plaintiffs from engaging in such practices;

F. That Apotex be award treble damages, attorneys' fees and costs pursuant to 15 U.S.C. § 15(a);

G. That Plaintiffs and their agents, representatives, attorneys and those persons in active concert or participation with them who receive actual notice hereof be enjoined from threatening or initiating infringement litigation against Apotex or its customers, dealers or suppliers, or any prospective or present sellers, dealers, distributors or customers of Apotex, or charging them either orally or in writing with infringement of any patent asserted against Apotex;

H. That Apotex be awarded such other and further relief as the Court deems just and proper.

Respectfully submitted,

HILL WALLACK LLP

Attorneys for Defendant Apotex, Inc.

Dated: February 4, 2007

By: /s/Eric I. Abraham

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CERTIFICATE OF SERVICE

This is to certify that a true and correct copy of the foregoing **DEFENDANT APOTEX INC.'S AND APOTEX CORP.'S ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS** is to be electronically filed. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

February 4, 2008
Date

/s/Eric I. Abraham
Eric I. Abraham

LOCAL CIVIL RULE 11.2 CERTIFICATION

Defendants Apotex, Inc. and Apotex Corp., by their attorneys, hereby certify that the matter in controversy is also the subject of the following actions:

Caption/Docket No./Court

Teva Pharmaceutical Industries Ltd., et al. v. Dr. Reddy's Laboratories Inc. et al.,
07-2894 (GEB)/D.N.J.

Teva Pharmaceutical Industries Ltd., et al. v. Watson Pharmaceuticals, Inc.,
07-2895 (GEB)/D.N.J.

Teva Pharmaceutical Industries Ltd., et al. v. MOEHS IBERICA, S.L.,
07-2897 (GEB)/D.N.J.

Teva Pharmaceutical Industries Ltd., et al. v. Wanbury Limited,
07-2913 (GEB)/D.N.J.

Teva Pharmaceutical Industries Ltd., et al. v. Zydus Pharmaceuticals, Inc., et al.,
07-4942 (GEB)/D.N.J.

I certify that the foregoing statements made by me are true. I am aware that if any of the foregoing statements made by me are willfully false, I am subject to punishment. Executed on February 4, 2008.

/s/Eric I. Abraham
ERIC I. ABRAHAM

F.R.C.P. RULE 7.1 DISCLOSURE STATEMENT

ERIC I. ABRAHAM, of full age, under oath, hereby declares as follows:

1. I am a member of the Bar of the State of New Jersey and am admitted to practice before the United States District Court for the District of New Jersey.
2. I represent Defendants Apotex, Inc. and Apotex Corp.
3. Apotex Corp. is wholly owned by Aposherm, Inc. of Ontario, Canada. Aposherm Inc. is ultimately owned by Apotex Holdings Inc.
4. Apotex, Inc. is wholly owned by Apotex Pharmaceutical Holdings, Inc., which itself is ultimately owned by Apotex Holdings Inc.
5. No publicly held corporation owns 10% or more of any of the companies.

I declare that the foregoing statements made by me are true. I am aware that if any of the foregoing statements made by me are willfully false, I am subject to punishment. Executed on February 4, 2008.

/s/Eric I. Abraham
ERIC I. ABRAHAM